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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			SCHAETZLE, KENNEDY	
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/970,146
Filing Date: October 02, 2001
Appellant(s): LOVETT ET AL.

MAILED
JUL 13 2006
Group 3700

Thomas Obermark
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 20, 2006 appealing from the
Office action mailed October 5, 2005

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,514,237	MASEDA	2-2003
4,329,993	LIEBER et al.	5-1982

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Maseda (Pat. No. 6,514,237).

Regarding claim 1, the examiner considers the conductive platinum metal discussed in col. 5, lines 1-19 to constitute at least one electrode with the electroactive polymer (see claim 8) representing the rheometric material electrically coupled to the electrode. Platinum is considered to be capable of transmitting and receiving electrical signals to and from tissue due to its conductive and biocompatible nature.

Regarding claim 3, note col. 6, lines 4-7.

Regarding claim 4, the assembly of Maseda comprises a rheometric material layer between platinum anode/cathode electrodes. The outer surface of the electrode can arbitrarily be assigned as the side upon which the rheometric layer resides on top of.

Regarding claims 5 and 6 and claims with similar limitations, one can arbitrarily designate one side of the catheter body to constitute a first surface with the opposite side of the body constituting a second surface. Since the rheometric material can be attached to the body such as set forth in col. 5, lines 56-67, one strand or electrode (note the rejection of claim 1) can be placed in a groove on one side of the catheter, while another strand or electrode is placed in a groove on the opposite side.

Regarding claim 7, the applicant is not claiming a pulse generator, but merely a lead body configured to be coupled to a pulse generator. The fact that the electroactive material at the distal end of the device body must be connected to a power supply at the

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proximal end as per col. 5, lines 40-55 dictates that the lead body be configured to be coupled to a pulse generator.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lieber et al. (Pat. No. 4,329,993) in view of Maseda

Lieber et al. disclose a medical device comprising an elongate device body and at least one electrode 35 coupled thereto for stimulating and sensing. Lieber et al., however, do not disclose the use of an assembly coupled with the device body including a rheometric material that contracts and/or stiffens when electrical current is applied thereto. Maseda, however, teaches that the use of such an assembly (including an electroactive material as set forth in claim 69) on a wide range of medical devices including the type disclosed by Lieber et al. is advantageous from the standpoint of increasing flexibility and steerability of the catheter as it is introduced into the body. Increased maneuverability through the tortuous vasculature system, high precision, and ease of placement –very important design considerations for the medical artisan-- make the incorporation of the Maseda assembly and related control system on the medical device of Lieber et al. an obvious choice. Related comments apply to claims 23 and 28.

Regarding claims 10, 26 and 60, see col. 5, lines 40-55 and col. 8, lines 33-36 of Maseda.

Regarding claims 12-14, 58 and 59, Maseda discloses that the assembly material may be disposed about the device body in a variety of arrangements including wrapping the material about the outer surface of the body, and using a plurality of assemblies.

Regarding claim 16, it is axiomatic that one desiring to control the insertion of a medical device would want to control the distal tip to prevent tissue damage and permit maximum maneuverability. To place the assembly about the distal tip would have been considered blatantly obvious.

Regarding claims 22 and 33, one can consider port 36 to be a preformed curved length portion.

Regarding claims 61 and 62, note col. 6, lines 7-12 of Maseda.

Regarding claims 63 and 67, the assembly of Maseda comprises a rheometric material layer between platinum anode/cathode electrodes. The outer surface of the electrode can arbitrarily be assigned as the side upon which the rheometric layer resides on top of.

Regarding claim 65, comments related to those made above in the rejection of claim 9 apply here as well, wherein the second electrode is considered to be one of the platinum electrodes of the Maseda assembly (see the rejection of claim 1 above).

Regarding claim 66, both electrodes must inherently be electrically coupled if they are to function as electrodes (i.e., they must be either coupled to a source of energy in order to activate the rheometric assembly or stimulate the electrode 35). Related comments apply to claim 68.

(10) Response to Argument

Regarding the rejection of claims 1 and 3-8, the examiner applies the principle of inherency. A claim feature is inherently met by a reference only if the feature is necessarily present in the reference. Transclean Corp. v. Bridgewood services Inc., 290 F.3d 1364, 1373, 62 USPQ2d 1865, 1871 (Fed. Cir. 2002). It is not sufficient for inherency that a result may occur - it must invariably happen. Scaltech Inc. v. Retec/Tetra. LLC., 178 F.3d 1378, 1384, 51 USPQ2d 1055, 1059 (Fed. Cir. 1999); see also MEHL/Biophile International Corp., Milgraum, 192 F.3d 1362, 1365, 52 USPQ2d 1303, 1305 (Fed. Cir. 1999). But the examiner's burden is not mile high. The examiner need only establish that the feature at issue is necessarily there by a preponderance of the evidence.

In reference to claim 1 (the rejection of claims 3-6 and 8 stand or fall with the rejection of claim 1 as the appellants have not individually argued these claims), the appellants state that they cannot find at least one electrode coupled with the device body that is configured to transmit and receive electrical signals to and from tissue. The examiner again refers the appellants to col. 5, lines 1-23 which explicitly refers to the use of ion-exchange polymer-noble metal composites (IPMC) including dendritic-type deposited electrodes of platinum coupled to the device body. The appellants further argue that the conductive platinum electrode of Maseda is not shown as being configured to transmit and receive electrical signals to and from tissue. It is unclear how the appellants can reasonably take such a position, when their very own disclosure (page 11, lines 10-14) states:

The electrode assembly 120 includes rheometric material associated therewith. For instance, the electrode assembly 120 includes a layer of an electrically active polymer 122 with electrodes 124 deposited thereon. Examples of suitable electrically active polymers include, but are not limited to, nafion, flemion, *ionic polymer metallic composite (IPMC)* [emphasis added]...

The appellants' disclosure further goes on to state (page 18, lines 3-7):

The electrodes 524, which are electrically coupled with a conductor of the lead 500, comprise a metallic coating which is deposited on opposite surfaces 526, 528 of the layer of electrically active polymer 522. In one example, the metallic coating is comprised of *platinum* [emphasis added].

The Board's attention is also invited to the appellants' admission on page 11, lines 1-9 of the present invention's specification that discloses that the same electrode used to stiffen the device body is capable of applying electrical signals to and from tissue. In view of the appellants' above admissions, it is unclear why the appellants' ionic polymer metallic composite (IPMC) material with platinum electrodes deposited thereon is capable of transmitting and receiving electrical signals, while the prior art's IPMC material with platinum dendritic anode/cathode electrodes deposited thereon is supposedly incapable of transmitting and receiving electrical signals. In fact, in order for the electrode assembly of Maseda to work, it *must* inherently be capable of receiving and transmitting electrical signals in order for the requisite electrical field as discussed

in col. 4, lines 55-57 and col. 5, lines 8-19 to be created and concomitantly allow the rheometric material sandwiched between the anode and cathode to cause the assembly to bend and flex (the examiner also wishes to point out that the voltage required to produce the necessary electric field in the Maseda device is taught to be 2 volts or higher (col. 5, lines 8-10), and is of the same magnitude as that proposed by the appellants' on page 18, lines 11-14 of their specification). Maseda further teaches that such materials in strip or strand form can be attached to the *outer* tubular body 114 and can be bonded to the *surface* of the outer tubular body (col. 5, lines 20-23 and 56-64) thus placing the material in a position to contact tissue. For one to accept the appellants' notion that the electrode assembly of Maseda operates in a different manner than the current invention, one must be willing to accept the outlandish conclusion that two different sets of physical laws apply—one for the prior art, and one for the appellants' invention. Unless the physical laws of nature that apply to the appellants' device do not apply to the Maseda device (which the appellants and their attorney obviously have failed to prove), the examiner can only come to the very reasonable conclusion that either the appellants have inadequately disclosed their invention, or both the appellants' device and the prior art's device are configured to transmit and receive electrical signals to and from tissue.

The examiner further cannot find in the claim where it is stated that the electrode *must* perform transmission and reception of electrical signals to and from tissue. The examiner, for example, cannot find any structure in the claim for generating such signals and sensing such signals. The electrode only need be *capable* of such action. Platinum electrodes are inherently capable of transmitting and receiving electrical signals to and from the body due to their conductive and biocompatible nature as known by anyone of ordinary competence in the medical or metallurgical arts. The applicants state in their own specification that platinum can be used as an electrode to conduct electricity (page 14, lines 14-24). The platinum electrode of Maseda can be attached to the outer tubular body 114 enabling it to come into contact with tissue or conductive bodily fluids. The platinum electrode of Maseda is thus capable of transmitting and receiving electrical signals to and from the tissue.

By analogy, a claim directed to a diamond configured to cut glass would be met by a reference showing a diamond ring –whether or not the reference set forth a means for, or a step of, grinding the diamond ring against glass. By its very nature the diamond is configured or capable of performing this function. In the same manner, the word *electrode* by its very definition pertains to a conductor used to establish electrical contact with a nonmetallic part of a circuit. The electrode is thus configured to establish electrical contact to and from tissue (the tissue being a nonmetallic part of the circuit). There is no reason to believe (and the appellants' certainly haven't provided any evidence to the effect) that Maseda intended to give the term any special meaning that would preclude application of this common definition.

In summary, the prior art device suggests the use of IPMC as a rheometric material; the appellants suggest the use of IPMC as a rheometric material. The prior art device suggests the use of deposited platinum electrodes on the IPMC; the appellants suggest the use of deposited platinum electrodes on the IPMC. The prior art suggests application of the composite electrode assembly on the outer surface of an elongated device body; the appellants suggest application of the composite electrode assembly on the outer surface of an elongated device body. The prior art suggests the use of a voltage signal of at least 2 volts to create an electrical field for application to the rheometric material; the appellants suggest the use of a voltage signal of at least 2 volts to create an electrical field for application to the rheometric material. The prior art suggests application of the invention to manipulating elongated medical devices within the cardiovascular system; the appellants suggest application of the invention to manipulating elongated medical devices within the cardiovascular system. By any measure, the examiner has clearly established that a preponderance of the evidence supports the inherency basis of his rejection. As the appellants and their attorney have failed to provide a scintilla of evidence to the contrary, it is thus submitted that a prima facie case of inherency has been established and the burden is on the appellants to prove otherwise.

Regarding the rejection of claim 7 under 35 U.S.C. §102(e), the appellants argue that they cannot find a device body that comprises an elongated lead body configured to be coupled with a pulse generator, despite the fact that the examiner has clearly pointed out col. 5, lines 27-55 of the Maseda reference. The appellants state that the examiner has failed to properly characterize the teachings of Maseda, and that the Maseda reference does not teach, "...the identical invention in as complete detail as contained in claim 7 as required by *In re Bond* and *Richardson v. Suzuki Motor Co.*" The appellants further state that the examiner is merely making conclusory statements, and request that the examiner submit an affidavit providing support for the assertion.

The examiner counters that the appellants have failed to properly characterize their invention and are impermissibly attempting to read limitations into the claim. Claim 7 is *not* directed to an elongated lead body in combination with a pulse generator. Claim 7 merely recites an elongated lead body *configured to be coupled with* a pulse generator. In order for the elongated lead body of Maseda to apply the requisite electrical control signals from control module 300 to the rheometric material via electrical conduit 302 (see Fig. 3), artisans of ordinary competence would understand that the elongated lead body of Maseda absolutely, positively *must* be configured to be coupled with an electrical signal generator (note the proximal end 120 of the elongated lead body with conduit access port 304). The fact that the appellants refer to the generator as a *pulse* generator makes no structural difference whatsoever because: (a) the appellants' claim does not set forth a pulse generator, and (b) a lead body configured to be coupled to a source of electrical energy is inherently capable of being connected to a pulse generator. It is unclear, for example, what structural difference it makes that the intended generator is a pulse generator. It is unclear why one would be prevented from connecting a pulse generator to the conduit access port 304, and the appellants have failed to provide any evidence to the contrary. A wire is capable of transmitting whatever form of electrical signal so happens to be connected to it. By analogy, a highway configured to carry gasoline-powered vehicles can also by default carry hybrid gas-electric or diesel-powered vehicles without modification.

The examiner considers the above reasoning to be sufficient in and of itself to support the rejection of claim 7, but will further argue that the signal generator of Maseda can reasonably be considered a pulse generator. Maseda discloses that when an electric voltage is applied to the rheometric material, the material will bend or twist, and when no voltage signal is applied, the material will relax (see col. 6, lines 30-36). By turning on and off this control voltage in order to selectively bend and relax the tip such as might be done to maneuver around an obstacle, one is by default pulsing the control signal on and off. The control module 300 is thus a pulse generator.

The examiner is further under no obligation to the appellant to provide an affidavit when a preponderance of evidence establishes the inherency of the feature. The burden rather shifts to the appellants. MPEP 2112.01 states:

“[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency’ under 35 U.S.C. 102, on prima facie obviousness’ under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted].” The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

As the appellants have failed to provide any convincing, subjective evidence to support their conclusions, the rejection must stand.

Regarding the rejection of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-69 under 35 U.S.C. §103, the appellants argue that the combination of Maseda and Lieber et al. would impermissibly change the principle of operation of the Lieber et al. device. The appellants state that the soft, pliable catheter body of Lieber et al. is advanced into the pulmonary artery via an inflated balloon mechanism and therefore does not require the precise navigational capabilities of the Maseda positioning system.

Despite the appellants’ contention, the examiner rebuts that there is indeed clear and explicit motivation for one of ordinary skill in the art to combine Lieber et al. and Maseda. The soft, pliable catheter body of Lieber et al. is intended for placement within the pulmonary artery—a widely recognized anatomically difficult region of the

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cardiovascular system to reach due to the fact that one typically must tortuously double-back the catheter body from the tricuspid valve 16 (see Fig. 1 of Lieber et al.) through the pulmonary valve 17 and into the curved pulmonary artery 18 while the heart is beating. Maseda explicitly teaches in the paragraph abridging cols. 5 and 6 that the improved positioning system is advantageous when one desires to place a soft, pliable tubular body within an artery that may be blocked or narrowed such as might occur due to stenotic lesions. Quoting from Maseda (col. 6, lines 7-18):

In another alternate embodiment, multiple composite strands may be incorporated into selected sections of the outer tubular body 114 and selectively activated such that some sections remain pliable and soft and other sections become rigid and pushable. In this manner, a high degree of steerability may be achieved. For example, in the situation where an artery is blocked with tight stenotic lesions and those blockages are in a curved area of the artery, the tip of the catheter 110 may be made soft and pliable while an adjacent portion may be made rigid, thereby providing steerability via the tip and pushability via the adjacent portion.

Pulmonary artery stenosis is a notoriously well-known and common heart ailment involving blockage or narrowing of the artery, causing concomitant reduced blood flow and cardiac output (one need only type the term into any Internet search engine to find hundreds of thousands of hits including reputable, well-esteemed sources discussing this condition). Since the device of Lieber et al. is intended for placement within the pulmonary arteries of patients suffering from cardiovascular and pulmonary diseases in an effort to properly diagnose and quantify their condition, it would not be unreasonable to expect to find stenotic lesions and other health-affecting blockages of the pulmonary artery. Anyone of ordinary skill in the art would have readily seen the provision of a navigational system to enable one to selectively and precisely steer a soft, pliable catheter body such as disclosed by Lieber et al. around a blockage in order to enable placement of the catheter body in the proper location, to be a decided advantage. The appellants' argument that such a modification would somehow change the principle of operation of the Lieber et al. system is not well understood or expressed. The examiner knows of no valid reason why skilled artisans would consider the two systems to be mutually exclusive. Precise medical devices as well as common every-day items

frequently incorporate both course adjustment and fine-tuning systems to no detriment (e.g., stereo tuners, microscopes, televisions, etc., all allow for course and fine-tune adjustment to effectively zero in on the correct setting or equipment placement). It is unclear why a medical device, where precise placement of sensor structure is often crucial to proper diagnosis and treatment, would be any different. The passive balloon placement system of Lieber et al., for example, may not allow proper placement of the distal sensor if the soft, pliable device body encounters an arterial blockage, or is hampered in reaching its final intended position by insufficient blood flow as caused by a restriction resulting in insufficient propulsion forces. Contrary to the appellants' baseless assertions, given the intended use of the Lieber et al. device and the explicit teaching by Maseda as elaborated above in a substantially related device, the examiner has clearly established a *prima facie* case of obviousness. The burden rests on the appellants to prove their case and they have failed. In view of the above reasoning and failure of the appellants and their attorney to effectively argue their position, the examiner requests that the rejection be maintained.

The appellants and their attorney further argue that there is no objective reason to combine Lieber et al. with Maseda. In support, it is argued that the Final Office Action does not state how Maseda would be in need of at least one electrode coupled with the device body where the at least one electrode is configured to transmit and receive electrical signals to and from tissue.

The examiner argues that the appellants' attorney is confusing the entire basis of the §103 rejection, thus rendering this argument totally moot. The examiner did not reject the claims under Maseda in view of Lieber et al., but rather under Lieber et al. in view of Maseda. Contrary to the appellants' assertion, the examiner is under no obligation to provide a reason for why it would be desirable to modify a secondary reference in this manner (although the examiner readily could), because the examiner is not relying on the Maseda reference to provide this supposedly missing feature as the base reference clearly incorporates the desired at least one electrode configured to transmit and receive electrical signals to and from tissue. See col. 4, lines 17-21 of

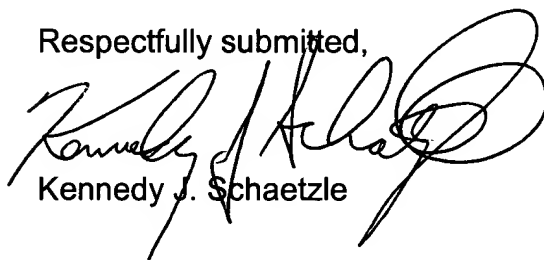
Lieber et al.. It is unclear how the examiner can be accused of improper hindsight when the base reference itself contains the identical feature.

The appellants further attempt to traverse the reasoning of the Final Rejection (page 24 of the Brief, first full paragraph) by repeating that the combination of Lieber et al. and Maseda would change the principle of operation for the Lieber et al. system. As argued above, such an assertion is baseless and unproven. All the arguments made by the examiner above apply here as well.

Finally the appellants argue that the examiner has not considered the invention as a whole and has instead seized on the differences and has used hindsight to consider them obvious. In an effort to apparently support their position, the appellants merely list the independent claims and repeat the statement that their claims include, in combination with all of the elements of the claim, at least one assembly including a rheometric material, the rheometric material contracts and/or stiffens when current is applied to it. It is unclear what point the appellants are attempting to make by simply highlighting the phrase, "in combination with all of the elements." The examiner clearly has considered the claims as a whole, has formulated a valid, reasonable *prima facie* case of obviousness based on explicit teachings in the prior art, and will let the record speak for itself.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,




Kennedy J. Schaetzle

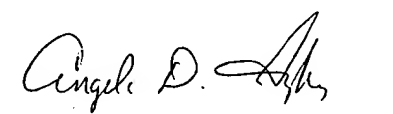
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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.